101st Congress
2d Session
HOUSE OF REPRESENTATIVES
Report
101-614

NATIONAL ORGAN TRANSPLANT PROGRAM EXTENSION ACT OF 1990

July 23, 1990.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed.

Mr. Dingell, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 5146]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5146) to amend the Public Health Service Act to revise and extend the program regarding organ transplantation, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
The Amendment	1
Purpose and Summary	4
Hearings	4
Committee Consideration	5
Committee Oversight Findings	5
Committee on Government Operations	5
Committee Cost Estimate	5
Congressional Budget Office Estimate	5
Inflationary Impact Statement	6
Section-by-Section Analysis and Discussion	7
Agency Views	11
Changes in Existing Law Made by the Bill, as Reported	13

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Organ Transplant Program Extension Act of 1990".

SEC. 2. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) SECTION HEADING.—Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended in the heading for the section by striking "ASSISTANCE FOR".

(b) AUTHORITY REGARDING CERTAIN GRANTS.—

(1) SPECIAL PROJECTS.—Section 371(a)(3) of the Public Health Service Act (42 U.S.C. 273(a)(3)) is amended by striking "may make grants for special projects" and inserting the following: "may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects".

(2) CONSIDERATIONS IN MAKING CERTAIN GRANTS.—Section 371(a) of the Public Health Service Act (42 U.S.C. 273(a)) is amended—

(A) in paragraph (4), by striking subparagraphs (A) and (C); and

(B) in paragraph (4), as amended by subparagraph (A) of this paragraph—

(i) by striking "Secretary shall—" and all that follows through "special consideration" and inserting "Secretary shall give special consideration"; and

(ii) by striking "organization, and" and inserting "organization.".

(c) SERVICE AREA OF QUALIFIED ORGAN PROCUREMENT ORGANIZATIONS.—

(1) IN GENERAL.—Section 371(b)(1)(E) of the Public Health Service Act (42 U.S.C. 273(b)(1)(E)) is amended to read as follows:

"(E) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,".

(2) ISSUANCE OF PERFORMANCE CRITERIA BY SECRETARY.—Section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) is amended—

(A) by redesignating paragraph (2) as paragraph (3); and

(B) by inserting after paragraph (1) the following new paragraph:

"(2) Not later than 180 days after the date of the enactment of the National Organ Transplant Program Extension Act of 1990, the Secretary shall issue performance criteria specifying the manner in which the Secretary determines whether the requirements established in paragraph (1)(E) have been met.".

(3) CONFORMING AMENDMENT.—Section 402(c)(3) of Public Law 100-607 (42 U.S.C. note), as amended by Public Law 101-274, is repealed.

(d) TECHNICAL CORRECTION REGARDING PUBLIC LAW 100-607.—Section 402(c)(2) of Public Law 100-607 (102 Stat. 3115) is amended by inserting "at the end" after "the comma".

SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) IN GENERAL.—Section 372(a) of the Public Health Service Act (42 U.S.C. 274(a)) is amended by striking the last sentence.

(b) MINIMUM QUALIFICATIONS OF CONTRACTOR.—

(1) IN GENERAL.—Section 372(b)(1)(A) of the Public Health Service Act (42 U.S.C. 274(b)(1)(A)) is amended by striking "which is not engaged in any activity unrelated to organ procurement" and inserting "with expertise in organ procurement".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect December 31, 1990.

(c) TECHNICAL CORRECTION.—Section 372(b)(2)(F) of the Public Health Service Act (42 U.S.C. 274(b)(2)(F)) is amended by striking "compatability" and inserting "compatibility".

SEC. 4. TRANSFER OF PROGRAM FOR BONE MARROW REGISTRY.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) by striking section 373(b); and

(2) in subpart 2 of part C of title IV, by adding at the end the following new section:

"NATIONAL BONE MARROW DONOR REGISTRY

"SEC. 424. (a) The Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

"(b) In addition to any other amounts authorized to be appropriated for the purpose of carrying out subsection (a), there are authorized to be appropriated for such purpose $15,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.".

Public Laws : 101st Congress / 2nd Session / House Reports / 1990

(b) CONFORMING AMENDMENT.—Section 373 of the Public Health Service Act, as amended by subsection (a) of this section, is amended—

(1) by striking the subsection designation; and

(2) in the heading for the section, by striking "AND BONE MARROW REGISTRY".

SEC. 5. GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS.

Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in subsection (a), in the first sentence, by striking "No grant" and all that follows through "373" the second place such term appears and inserting the following: "No grant or contract may be made under this part";

(2) in subsection (b)—

(A) by striking paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively;

(B) in paragraph (1) (as so redesignated), by striking "section 371" and inserting "section 371(a)(1)";

(C) in paragraph (2) (as so redesignated), in the first sentence, by striking "paragraphs (2) and (3) of section 371(a)" and inserting "section 371(a)(2)"; and

(D) by adding at the end the following new paragraph:

"(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years."; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in the first sentence, by inserting "or contract" after "grant"; and

(ii) in the second sentence, by inserting "and contracts" after "grants" each place such term appears; and

(B) in paragraph (2), in subparagraphs (A) and (B), by inserting "or contract" after "grant" each place such term appears.

SEC. 6. ADMINISTRATION.

(a) IDENTIFIABLE ADMINISTRATIVE UNIT.—Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended in the matter preceding paragraph (1) by striking "1990," and inserting "1993,".

(b) STRIKING OF EXPIRED REQUIREMENT REGARDING CERTAIN REPORTS.—Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended—

(1) by striking paragraph (4); and

(2) by adding "and" after the comma at the end of paragraph (2), and by striking "transplants, and" at the end of paragraph (3) and inserting "transplants.".

SEC. 7. REPORT.

Section 376 of the Public Health Service Act (42 U.S.C. 274d) is amended in the first sentence by striking "The Secretary" and all that follows through "publish a report" and inserting the following: "Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish a report".

SEC. 8. STUDY BY GENERAL ACCOUNTING OFFICE.

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by adding at the end the following new section:

"STUDY BY GENERAL ACCOUNTING OFFICE

"SEC. 377. (a) The Comptroller General of the United States shall conduct a study for the purpose of determining—

"(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective; and

"(2) the problems encountered in such procurement and allocation, particularly for racial and ethnic minorities.

"(b) Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study."

SEC. 9. ESTABLISHMENT OF SINGLE AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Part H of title III of the Public Health Service Act, as amended by section 8 of this Act, is amended by adding at the end the following new section:

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 378. For the purpose of carrying out this part, there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.".

(b) CONFORMING AMENDMENT.—Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended by striking subsection (c).

SEC. 10. EFFECTIVE DATE.

Except as provided in section 3(b)(2), the amendments made by this Act shall take effect October 1, 1990, or upon the date of the enactment of this Act, whichever occurs later.

PURPOSE AND SUMMARY

The purpose of H.R. 5146 is to extend for 3 fiscal years the authorization of appropriations for expiring programs of the National Organ Transplant Program. The program is operated by the Division of Organ Transplantation within the Department of Health and Human Services' Health Resources and Services Administration. The Division is responsible for supporting a program of special project grants to increase the donation of organs and establishment of new organ procurement organizations; a scientific registry of organ transplant recipients; and the Organ Procurement and Transplantation Network. The Division is also responsible for providing technical assistance to organ procurement organizations and preparing an annual report on the efficiency and effectiveness of organ procurement activities; $5 million is authorized for these activities in each of fiscal years 1991–93.

The legislation also extends for an additional 3 fiscal years the National Marrow Donor Program operated by the National Heart, Lung and Blood Institute; $15 million is authorized for the purpose of donor recruitment and blood typing in fiscal year 1991 and such funds as may be necessary in 1992–93. The authorization is sufficient to achieve the goal of registering 250,000 marrow donors. The bone marrow registry is operated by the National Heart, Lung and Blood Institute of the National Institutes of Health.

In addition, the legislation revises two required reporting requirements. The annual report of the Secretary to report on the scientific and clinical status of organ transplantation is revised to be a biennial report. The annual report of the Division of Organ Transplantation on the status of organ donation is repealed and replaced with a single, triennial report of the General Accounting Office.

HEARINGS

The Committee's Subcommittee on Health and Environment held 1 day of hearings on H.R. 5146 on Friday, April 20, 1990. Testimony was received from five withnesses, representing the U.S. House of Representatives, Health Resources and Services Administration, National Institutes of Health, and Health Care Financing Administration, with additional material submitted by individuals and organizations representing organ procurement associations and various medical societies.

Committee Consideration

On Wednesday, June 20, 1990, the Subcommittee on Health and the Environment met in open session and ordered reported the bill H.R. 5146, by a voice vote, a quorum being present. On Wednesday, June 27, 1990, the Committee met in open session and ordered reported the bill H.R. 5146 with amendments by voice a quorum being present.

Committee Oversight Findings

Pursuant to clause 2(l)(3)(A) of Rule XI of the Rules of the House of Representatives, no oversight findings or recommendations have been made by the Committee.

Committee on Government Operations

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

Committee Cost Estimate

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that the bill will authorize $20 million in spending for fiscal year 1991 and such funds as may be necessary in fiscal years 1992 and 1993.

Congressional Budget Office Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, July 19, 1990.

Hon. John D. Dingell,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for H.R. 5146, the National Organ Transplant Program Extension Act of 1990, as ordered reported by the House Committee on Energy and Commerce on June 27, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert D. Reischauer,
Director.

Attachment.

1. Bill number: H.R. 5146.
2. Bill title: National Organ Transplant Program Extension Act of 1990.
3. Bill status: As ordered reported by the House Committee on Energy and Commerce on June 27, 1990.
4. Bill purpose: To amend the Public Health Service Act to revise and extend the program regarding organ transplantation.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
Organ procurement and transplantation activities	5	5	5		
Bone marrow registry	15	16	16		
Total estimated authorization levels	20	21	22		
Estimated outlays:					
Organ procurement and transplantation activities	3	5	5	2	1
Bone marrow registry	7	14	16	9	2
Total estimated outlays	9	18	21	11	2

Details in this table may not add to totals because of rounding. The costs of this bill fall within budget function 550.

Basis of Estimate

H.R. 5146 would authorize funds to establish and operate organ procurement organizations, an organ procurement and transplantation network, and a scientific registry of the recipients of organ transplants. In addition, the Secretary of Health and Human Services (HHS) would have to report every two years on the scientific and clinical status of organ transplantation. The bill provides $5 million in fiscal year 1991, and such sums as may be necessary in fiscal years 1992 and 1993 for these activities.

H.R. 5146 would also authorize the Secretary of HHS to establish a registry of voluntary bone marrow donors. The bill provides $15 million in fiscal year 1991, and such sums as may be necessary in fiscal years 1992 and 1993 for the establishment of the registry.

The 1992 and 1993 authorizations have been estimated by increasing the 1991 levels for projected inflation.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: C.G. Nuckols for James L. Blum, Assistant Director for Budget Analysis.

Inflationary Impact Statement

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee makes the following statement with regard to the inflationary impact of the reported bill:

It is not anticipated that H.R. 5146 will have a significant inflationary impact upon the economy. Organ transplantation is a life-saving procedure for thousands of patients. In the case of patients with end-stage renal disease, transplantation can not only restore normal life activities, but it can eliminate Federal expenditures for disability payments and Medicare costs for dialysis treatments. Improvements in the availability and quality of organ transplantation

may, on balance, have a deflationary effect on the economy over the long term.

Section-by-Section Analysis

"National Organ Transplant Program Extension Act of 1990"

SECTION 1. SHORT TITLE

The committee bill may be cited as the "National Organ Transplant Program Extension Act of 1990."

SEC. 2. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

Subsection (a) revises the heading of Section 371 of the Public Health Service Act (PHSA).

Subsection (b) expands the eligibility criteria for awarding special project grants to include nonprofit private entities in addition to qualified organ procurement organizations, and revises the priorities for awarding grants.

Under existing law grant are authorized for the planning, establishment, initial operation and expansion of OPOs. In addition, grants are authorized for special projects undertaken by OPOs that are designed to increase the number of organ donors.

The Committee bill amends current law to allow other private, non-profit entities to be awarded grants or contracts to support special studies or projects to increase the number of organ donors. The Committee intends that grants for OPO planning, establishment, initial operation, consolidation and expansion continue to be available as may be required to improve the effectiveness of organ procurement. Therefore, the Committee bill would extend the authorization of appropriations for 3 years under the consolidated authorization contained in Section 9.

The Committee bill also would revise existing law to continue special consideration by the Secretary to grant applications from qualified OPOs in geographical areas which are not adequately served, and remove certain preferences for awarding grants that are outdated and no longer appropriate.

Subsection (c) of the Committee bill would delete the requirement set forth in current law that the area served by an OPO be sufficiently large that it can reasonably be expected to procure organs from at least 50 donors per year. This provision was designed to promote efficiency and effectiveness in the retrieval of organs. To be effective, OPOs must have sufficient resources to hire a core group of competent employees. This argues against allowing small OPOs, which might not have the resource base to be effective. In addition, OPOs should be held accountable for a vigorous effort, measured by clear performance standards. It was for these reasons that the original National Organ Transplant Act of 1984 was amended by Section 402(c) of the Health Omnibus Programs Extensions Act of 1988 (P.L. 100–607) to establish a higher standard of performance than included in the original Act.

However, this provision of current law has not yet been implemented. Under the 1988 amendments, the effective date for meeting the 50 donor minimum was delayed until 2 years after the initial designation of the OPO, or April 1, 1990. Subsequently, the

Committee learned that a substantial number of OPOs would not have satisfied this requirement as of the effective date. Because failure to meet this standard would result in OPOs being ineligible for Medicare or Medicaid payments, the system for organ retrieval might have been seriously disrupted. Therefore, the effective date was again extended until January 1, 1992 by Public Law 101-274. This extension was intended not only to give OPOs more time to come into compliance with this requirement, but also to give the Committee more time to review this issue thoroughly.

As a result of thest developments, the Committee bill would remove a numerical standard for organ donors from the statute, and repeal the provision of Public Law 101-274 regarding a new effective date. In its place, the bill requires the Secretary to establish explicit performance standards by regulation within 180 days of the enactment of these amendments.

This change does not represent a major shift in the Committee's views about the appropriate size of OPOs, but rather a change in the approach to achieving the objective of efficient and effective OPOs. It is still the view of the Committee that there should not be OPOs that retrieve organs from a narrow geographical base and in effect provide service to a single transplant center. It is also the Committee's view that metropolitan statistical areas (MSAs) should not be divided. In those circumstances where MSAs cross state lines, and the Secretary has determined that a statewide OPO is appropriate, the Committee believes the statewide OPO may include those portions of the MSA located in an adjacent state. In general, the Committee urges the Secretary to designate statewide OPOs wherever practicable, unless larger area designations would clearly be more cost effective.

The Committee expects the Secretary to promulgate performance standards under this provision that will promote both effectiveness and efficiency among OPOs. The Committee notes, in particular, that a standard of retrieving a specified number of organ donors per million population would not, by itself, satisfy these requirements. A small OPO might well be able to meet such a standard, but at an unacceptably high cost per organ. Moreover, since organ retrieval cannot be expected be uniformly successful, some OPOs, under this standard, might be able to serve areas of high yield, leaving other OPOs with the difficult task of trying to succeed in areas of low yield.

Subsection (d) of the Committee bill includes a technical correction to Public Law 100-607 regarding representation on the board of a qualified OPO.

SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Subsection (a) makes conforming change to existing law by deleting the general authorization of appropriations for the OPTN because of the consolidated authorization for this activity contained in Section 9 of the Committee bill.

Subsection (b) amends the minimum qualifications that must be met by an entity seeking the contract to operate the OPTN by deleting the requirement in existing law that such an entity must not

be engaged in any activity unrelated to organ procurement, effective with contracts entered into on or after December 31, 1990.

The role of the OPTN is critical in accomplishing the goals of this Act. In the extension of the Act under Public Law 100-607 in 1988, a number of modifications to the procedures of the OPTN were put into place. Specifically, the OPTN must establish membership criteria and medical criteria for allocating organs through a public process that allows for comments by interested parties, including patients, physicians, and providers, and follows, as closely as practicable, the procedures of federal agencies, such as the Health Care Financing Administration, in promulgating regulations, including the use of public hearings where appropriate. In addition, the 1988 Act directed the Secretary to establish procedures for receiving and considering comments from interested parties on the performance of the OPTN.

It is important to note that, by virtue of provisions included in the Omnibus Budget Reconciliation Act 1986 (P.L. 99-509), Medicare and Medicaid participating hospitals that perform organ transplant must be members of and abide by the policies of the OPTN. In addition, the costs of organ procurement and distribution imposed by an OPO on a transplant center are not reimbursable by Medicare or Medicaid unless the OPO is a member of the OPTN. These provisions are intended to protect transplant patients by assuring them equitable access to the limited supply of organs, and by assuring that transplant are performed in accordance with acceptable standards of medical practice.

The Committee bill, by modifying the minimum requirements for eligibility or future OPTN contractors, is intended to provide the Secretary with the opportunity to consider a broader array of potential applicants for this critical role. This change should not be interpreted as an expression of Committee opinion with respect to the performance of the current contractor. It is the Committee's intent that the Secretary have the opportunity to select contractors on the basis of their expertise in carrying out the duties and responsibilities of the OPTN, whether or not an entity is engaged in other activities. Since the current contract is scheduled to expire on September 30, 1990, the revised qualification language of the Committee bill does not affect the Secretary's decision in awarding a new contract this year.

SEC. 4. TRANSFER OF PROGRAM FOR BONE MARROW REGISTRY

Subsection (a) of the Committee bill would transfer the authority for establishing and maintaining a bone marrow donor registry from Section 373 to Section 424 of the Public Health Service Act, and would extend the authorization of appropriations for 3 fiscal years.

Bone marrow transplantation has been demonstrated to be effective and the treatment of choice for a growing number of patients with certain blood diseases. The major limit on the user of this therapy has been the lack of a matched relative donor or a matched unrelated donor. Congress recognized the need to create a national program to coordinate efforts to recruit potential donors, to centralize data on the blood characteristics of donors, and to en-

courage appropriate professional standards for the conduct of these procedures. After over 3½ years, initially under contract to the U.S. Navy and for the last year under contract with the NIH's Heart, Lung, and Blood Institute, the National Marrow Donor Program (NMDP) has established a registry of over 140,000 potential donors. There are 28 U.S. transplant centers approved for participation in the NMDP. As of January 1, 1990, 3,645 searches have been performed and some 260 transplants have been accomplished.

In order to create a donor pool of sufficient size to increase the porbability of a match for patients in need of a marrow transplant, the NMDP has established a goal of 250,000 potential U.S. donors, and with linkages to foreign registries, 1 million worldwide. To meet this goal, additional funds will be required to cover the costs of donor recruitment and blood typing.

The Committee bill provides a $15 million authorization of appropriations to support this national program in fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993. This represents an amount that is estimated to be required for the NMDP to reach its goal of 250,000 potential marrow donors. These funds are primarily used to pay the costs of blood typing and to assist in donor recruitment. The Committee believes that the responsibility for the contract with the NMDP should remain with the National Heart, Lung, and Blood Institute. The Committee clearly intends that the registry should operate in a manner that preserves donor confidentiality and informed consent. Sharing of data concerning the experience of centers performing marrow transplants should continue to be a condition of participation in the registry.

SEC. 5. GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

This section of the Committee bill would revise certain administrative requirements with respect to the grant and contract programs authorized under the Act.

Specifically, the Committee bill would continue the limitations imposed on planning grants for OPOs of $100,000 for a maximum of 1 year. The bill would also limit initial operation, consolidation, or expansion grants to OPOs to $500,000 per year, not to exceed 2 years and $800,000 in the aggregate. Finally, the Committee bill would limit special project grants to 3 years.

SEC. 6. ADMINISTRATION

Subsection (a) of the Committee bill would extend for 3 years the requirement in existing law for the Secretary to maintain an identifiable administrative unit in the Public Health Service to administer programs under the Act, conduct a program of public information promoting organ donation, and provide technical assistance to OPO grantees, the OPTN, and other involved entities. The Division of Organ Transplantation is currently charged with these responsibilities under the Act, and is located within the Health Resources and Services Administration of the Department of Health and Human Services.

Subsection (b) deletes the requirement for the Secretary to submit to Congress an annual report on the status of organ dona-

tion and coordination, including an evaluation of the efficiency and effectiveness of the procurement and allocaiton of organs. This report is replaced by a special study to be undertaken by the General Accounting Office, as specified in Section 8 of the Committee bill.

SEC. 7. REPORT

This Section of the Committee bill would revise the Secretary's annual reporting requirement with respect to the scientific and clinical status of organ transplants and direct that such a report be submitted every 2 years, beginning February 10, 1991 and thereafter.

SEC. 8. STUDY BY GENERAL ACCOUNTING OFFICE

This section of the Committee bill would create a new authority for the Comptroller General of the United States to conduct a study to determine (a) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective; and (b) the problems encountered in such procurement and allocation. The report is to be complted and submitted to Congress no later than January 7, 1992. This report was previously the responsibility of the Secretary of Health and Human Services and would be deleted by Section 6 of the Committee bill.

SEC. 9. ESTABLISHMENT OF SINGLE AUTHORIZATION OF APPROPRIATIONS

This section of the Committee bill would consolidate the authorization of appropriations for the national organ transplant program. The bill would authorize $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the next 2 fiscal years. The current authorization of appropriations for fiscal year 1990 is $5,000,000.

Agency Views

The Committee received the following letter expressing the Administration's views on H.R. 5146.

The Secretary of Health and Human Services,
Washington, DC, June 27, 1990.

Hon. John D. Dingell,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

Dear Mr. Chairman: We understand that your Committee will soon mark up several bills which reauthorize and amend programs administered by the Department of Health and Human Services. The Department would like to share its concerns on these bills with you and the other Members of your Committee.

The Orphan Drug Amendments of 1990 (H.R. 4638) would reauthorize the grants and contracts for orphan drug development and establish a shared exclusivity in cases where the drugs were developed simultaneously. The Administration submitted a bill report to the Health and Environment Subcommittee on June 20th objecting to the elimination of the 7 year exclusive marketing rights which we consider to be the key to the past success of this program. Al-

though we recognize changes to the bill were made in Subcommittee mark-up, the Administration continues to oppose H.R. 4638 and supports instead, a straight extension of the current program.

H.R. 4487 would reauthorize the National Health Service Corps (NHSC) until the year 2000 and make various administrative changes. The Department supports the continuation of this program and we believe some significant improvements in the bill were made in the recent Subcommittee mark-up. However, the Department strongly advocates several changes to the bill.

First, we would like the Committee to recognize that a major component of the Administration's minority health initiative as proposed in the President's 1991 Budget is to increase the request for funding for the NHSC in 1991 from $8.9 to $63.9 million for the loan repayment and scholarship program. In this regard, we request that the authorization of appropriations in Section 203 of the bill be revised from "sums as necessary" to read "$63,900,000." Such a change would send a clear signal that your Committee shares our view on the importance of the NHSC program in meeting our objectives for minority health as well as improving access to care for rural populations.

Second, we strongly object to the provision requiring the program to reimburse an additional amount for the tax liabilities incurred by loan recipients. As you know, current authority allows the Secretary to make such payments in whole or in part for these tax liabilities when requested and justified by special circumstances. We believe that extending this policy to all loan recipients is unwarranted and we favor the current flexible, discretionary policy.

Third, we object to earmarking a percentage amount of appropriated funds for new NHSC scholarships and for scholarships in selected health care fields. This provision restricts the Department's flexibility to allocate resources in accordance with changing needs and priorities. Rather than a mandatory earmark, the Administration would prefer to have discretion to distribute scholarships by field, and therefore, urges the Committee to delete the earmark provision in the bill.

Fourth, we are concerned about increasing the loan repayment ceiling to $35,000 per year of obligated service from the current level of $20,000 per year and the requirement for single year funding of NHSC scholarships. Raising the ceiling could increase the annual cost per NHSC placement and reduce the total number of placements that could be supported.

Finally, although we support the extension of the grants for state loan repayment programs, the Administration objects to provisions which attempt to increase Federal control over state-run programs. In particular, we strongly object to the provision adopted in Subcommittee which would restrict states from providing more favorable loan repayment arrangements than the NHSC. State programs should have the flexibility to determine how to allocate resources in addressing the health manpower shortages within the state.

The Administration supports the reauthorization of the organ transplantation programs. H.R. 5146 would extend these programs and make a number of program improvements that will make the

program easier to adminsiter in the future. We do not support, however, the magnitude of the increase in funding authority for the bone marrow registry contained in the bill.

The health programs for the homeless under the McKinney Act, which we support, are currently authorized through 1991. The Department believes that H.R. 3789, which would extend and expand these programs, is premature. In addition, we do not support the magnitude of the increased funding authority for homeless primary care grants.

Addressing the homeless problem requires program coordination. Reauthorization of the McKinney Act piecemeal will only make that goal elusive. The Administration has proposed a one-year extension of the appropriation authorities in the McKinney Act that expire this year, so they would be in synchronization with the other authorities in the Act. The Administration plans to send legislation to the Congress to extend and amend the entire McKinney Act next year.

The Administration supports the reauthorization of the CDC injury control program, although we do not support the increase in the authorization level included in H.R. 5073.

Mr. Chairman, I appreciate your full consideration of these comments as your Committee proceeds with action on these bills.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

LOUIS W. SULLIVAN, M.D.,
Secretary.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART H—ORGAN TRANSPLANTS

[ASSISTANCE FOR] ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. (a)(1) * * *

* * * * * * *

(3) The Secretary may make grants [for special projects] *to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for*

the purpose of carrying out special projects designed to increase the number of organ donors.

(4) In making grants under paragraphs (1) and (2), the [Secretary shall—

[(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act,

[(B) give special consideration] *Secretary shall give special consideration* to applications which cover geographical areas which are not adequately served by organ procurement organizations [, and

[(C) with respect to carrying out paragraph (3), give special consideration to proposals from existing organ procurement organizations.].

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragrah (2) and—

(A) * * *

* * * * * * *

[(E) has a defined service area which is a geographical area of sufficient size such that (unless the service area comprises an entire State) the organization can reasonably expect to procure organs from not less than 50 donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,]

(E) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

* * * * * * *

(2) Not later than 180 days after the date of the enactment of the National Organ Transplant Program Extension Act of 1990, the Secretary shall issue performance criteria specifying the manner in which the Secretary determines whether the requirements established in paragraph (1)(E) have been met.

[(2)] *(3)* An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations.

* * * * * * *

[(c) For grants under subsection (a), there is authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990.]

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Trans-

plantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $2,000,000. [Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.]

(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

(A) be a private nonprofit entity [which is not engaged in any activity unrelated to organ procurement] *with expertise in organ procurement*, and

* * * * * * *

(2) The Organ Procurement and Transplantation Network shall—

(A) * * *

* * * * * * *

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the [compatability] *compatibility* of such individuals with organ donors,

* * * * * * *

SCIENTIFIC REGISTRY [AND BONE MARROW REGISTRY]

SEC. 373. [(a)] The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

[(b)(1) Not later than October 1, 1988, the Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

[(2) For the purpose of carrying out paragraphs (1), there are authorized to be appropriated $1,500,000 for fiscal year 1989 and $1,600,000 for fiscal year 1990.]

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. 374. (a) [No grant may be made under section 371 or 373 or contract entered into under section 372 or 373] *No grant or contract may be made under this part* unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)[(1) In considering applications for grants under section 371—

[(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area,

[(B) the Secretary shall give special consideration to organizations which met the requirements of section 371(b) before the date of the enactment of this section, and

[(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

[The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.]

[(2)] *(1)* A grant for planning under section 371*(a)(1)* may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

[(3)] *(2)* Grants under [paragraphs (2) and (3) of section 371(a)] *section 371(a)(2)* may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant *or contract* made under section 371 or 373. Payments under such grants *and contracts* may be remade in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants *and contracts*.

(2)(A) Each recipient of a grant *or contract* under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records shich fully disclose the amount and disposition by such recipient of the proceeds of such grant *or contract*, the total cost of the undertaking in connection with which such grant *or contract* was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant *or contract* under section 371 or 373 that are pertinent to such grant *or contract.*

* * * * * * *

ADMINISTRATION

SEC. 375. The Secretary shall, during fiscal years 1985 through [1990,] *1993*, designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act,

(2) conduct a program of public information to inform the public of the need for organ donations, *and*

(3) provide technical assistance to organ procurement organizations receiving funds under section 371, the Organ Procure-

ment and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants[, and].

[(4) not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.]

REPORT

SEC. 376. [The Secretary shall, not later than October 1 of each year, publish a report] *Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish a report* on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

STUDY BY GENERAL ACCOUNTING OFFICE

SEC. 377. (a) The Comptroller General of the United States shall conduct a study for the purpose of determining—

(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective; and

(2) the problems encountered in such procurement and allocation, particularly for racial and ethnic minorities.

(b) Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

AUTHORIZATION OF APPROPRIATIONS

SEC. 378. For the purpose of carrying out this part, there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

* * * * * * *

TITLE IV—NATIONAL RESEARCH INSTITUTES

* * * * * * *

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

* * * * * * *

Subpart 2—National Heart, Lung, and Blood Institute

* * * * * * *

NATIONAL BONE MARROW DONOR REGISTRY

SEC. 424. (a) The Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

(b) In addition to any other amounts authorized to be appropriated for the purpose of carrying out subsection (a), there are authorized to be appropriated for such purpose $15,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

* * * * * * *

SECTION 402 OF THE ORGAN TRANSPLANT AMENDMENTS ACT OF 1988

SEC. 402. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) * * *

* * * * * * *

(c) DESCRIPTION OF ORGAN PROCUREMENT ORGANIZATION.—

(1) * * *

(2) Section 371(b)(1)(G)(i)(III) is amended by inserting before the comma, *at the end* the following: "or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility".

[(3) The amendment made by paragraph (1)(A) shall not apply to an organ procurement organization designated under section 1138(b) of the Social Security Act until 2 years after the initial designation of the organization under such section.]

* * * * * * *

○

CMS LIBRARY
3 8095 00012627 2